Remarks

Following entry of this Amendment, claims 21, 24-36, 29, and 32-34 are pending. Claims 1-20, 22, 23, 27, 28, 30, 31, 35, and 36 are cancelled.

The Office Action mailed April 16, 2008 rejects each of the pending claims 21, 22, 24-30, and 32-36. Claim 22 is rejected under §112, second paragraph. Claims 21, 22, 24-30, and 32-36 are rejected under §103(a) as obvious over **Patel et al** (WO 01/37808) in view of **Friedman** ((US 3,824,233) or **Malnoe et al** (WO 02/71874) or **Alford** (US 3,937,825) or **Thombre et al** (US 2003-0190343). Applicants address the rejections in the order in which they were presented.

35 USC §112

Claim 22 is cancelled. The rejection of claim 22 is rendered moot.

35 USC §103

With reference to the specification as filed, the present invention is concerned with a composition in pellet or tablet form for use in administering medicines to animal as a part of feed consumption. While the Examiner recognizes that the *rationale* for preparation between the present invention and the prior is different, he goes on to argue that the different functions may be ascribed to the same dosage form. This assumption is incorrect.

As identified in the specification as filed, the rationale for preparation is precisely why the prior art compositions fail. As noted in the specification

> In the case of a human patient, an unpleasant tasting active ingredient can be masked relatively easily, e.g., by coating it with a neutral-tasting or sweet layer. ... It is easy to instruct the human patient to take the preparation without chewing.

With regard to veterinary compositions, however, many human application forms are unsuitable for animal medicine. The eating habits of animals play a decisive role when using oral application forms. A useful exemplary subject is a cat. Cats do not exactly chew their food. Generally they use their teeth to break their food it into smaller pieces and then swallow. The breakage would thus damage any protective coating of a table or capsule and release the unpleasant tasting active ingredient, in this case benazepril.

The present application provides an intimate mixture of (i) animal feed, for example yeast; and (ii) particles of a **specific** size which are coated -- first with benazepril and second with a masking protective layer. In this manner, the overall composition may be

ingested, as feed consumption, without exposing the bitter-tasting active ingredient to the gustatory cells of the animal's mouth.

The Examiner cites *KSR*, but fails to appreciate a key component of the Supreme Court's reasoning in *KSR* is that the information in the prior art yielded predictable results.

> A rationale to support a conclusion that a claim would have been obvious is that all the claimed elements were known in the prior art and one skilled the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art. *KSR International Co. v. Teleflex,* 82 USPQ2d 1385.

In this case, there is absolutely no reasonable expectation of success from the cited references.

Patel et al disclose a pharmaceutical composition for use in humans. The final product may be swallowed – and there is no appreciation or discussion of a composition subject to breakage during consumption. **Patel et al** disclose particles that are coated with an active ingredient. But, mixtures of said particles with an animal feed substrate, such as yeast, are not proposed or disclosed anywhere. Thus, the particle size, as claimed in the present invention, is of no concern at all in the **Patel et al** reference. Without a recognition of the problem to be solved, there can be no expectation of success in a solution.

Further, although benazepril is mentioned in the prior art document, there is no real focus on this specific drug, since it is only part of an immense list of all kinds of drugs. This disclosure by no means is a motivation to select a benazepril formulation. Further, there is no appreciation in the **Patel et al** reference of the pronounced bitter taste of benazepril and its use in veterinary applications. Moreover, without such appreciation there can be no suggestion for the need to make benazepril appealing to animals for feed consumption.

In addition, the **Patel et al** composition actually teaches away from the present invention. **Patel et al** requires particles to be coated with a combination of active ingredient and a hydrophilic surfactant. Please refer to the extensive disclosure of surfactants in the **Patel et al** reference. In strong contradiction thereto, the particles of the present invention are coated with the active ingredient, alone, and are then further protected by a second, discrete layer.

The presently claimed animal health product is a successful commercial product around the world. **Patel et al** is in a different technical field, namely dealing with human drugs in general. **Patel et al** provides no motivation to mask bitter tasting drugs that would

be subjected to breakage and exposure within the mouth. Accordingly, **Patel et al** fails as a starting point for an argument of prima facie obviousness.

The secondary references are insufficient to cure the deficiencies of the primary reference. Similar to **Patel et al**, **Alford** does not propose or suggest to intimately mix a feed substrate with drug coated particles. Further, Alford fails to recognize the unique problems associated with the specific active ingredient, benazepril, the specific size of the particles, or their specific coating.

Thrombe was not yet published on the filing date of the present application and is available, if at all, only under 35 USC §102(e). Nevertheless, **Thrombe** is not at all concerned with benazepril compositions. Moreover, there is not any hint about the specific structure of the claimed invention, in particular the particle size, the dual coating of the particles, or their intimate mixture with feed. Thrombe fails to provide any support to the primary reference.

Likewise, neither **Friedman** and **Malnoe** add anything regarding a benazepril composition which is acceptable to animals. Both references are totally remote and fail to provide any secondary support to the prima facie argument.

Accordingly, the presently claimed invention is not rendered obvious even by a combination of two or more of the cited references. None of the cited references discloses the specific structure of the inventive composition, including the size range and specific bitter component. Applicants believe the present claims are in condition for allowance and respectfully request such action. If the Examiner has any remaining issues for resolution, he is encouraged to telephone the undersigned for expeditious handling.

Respectfully submitted,

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Amy H. Fix
Reg. No. 42,616
Womble Carlyle Sandridge & Rice,PLLC
Post Office Box 7037
Atlanta, Georgia 30357-0037
Telephone: (919) 484-214
Facsimile: (919) 484-2071